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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,365	08/28/2003	Guangwen Wei	#792-A-PCT-US	7677

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EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 03/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/650,365	Applicant(s) WEI ET AL.	
	Examiner Jegatheesan Seharaseyon, Ph.D	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is in response to Applicants remarks filed 11/28/2005, which has been entered. Applicants have cancelled 1-9, 11-16, 23-25 and 27-28. Applicants have submitted new claims 29-37 which are under consideration in the instant Office Action.

2. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Specification

3. Applicants amendments to the specification are noted with respect to providing SEQ ID numbers to the various oligos is noted. However, Applicants are held to be in **non compliance** with sequence disclosure rules set forth in 37 CFR 1.821(a)(1) and (a)(2) because Applicants have not provided SEQ ID number to the polypeptide fragment of disclosed on page 17, line 19. Applicants have also not provided a SEQ ID number for the polypeptide disclosed in pages 20-21. In addition, Applicants have not followed the correct format ("SEQ ID NO: X") to describe the various sequences. Claim 59 also lacks the proper format for reporting the sequence ID number. Correction is required.

Information Disclosure Statement

4. The Office has considered the resubmitted references in Exhibit A and B to the extent where there is translation (abstract) only. The examiner is unable to fully

Art Unit: 1647

consider the references in their entirety because it is in a foreign language which the examiner is not familiar with.

5. The supplemental information disclosure statement provided on 1/19/06 has been considered. However, if the Applicants wishes to have any of the references noted in the search report appear on the face of the patent they are required to provide the references in a PTO-1449.

Priority

6. The requirement for providing a translation is withdrawn.

Claim Objections

7. The objection to claim 11 is withdrawn because Applicants have cancelled the claim.

Claim Rejections - 35 USC § 112, second paragraph maintained

8. The rejection of claims 1, 4-9, 11 and 23-24 under 35 USC 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn and reapplied to pending claims 29-37 with respect to Applicants' recitation of "super-compound interferon". The Applicants canceling of the previously pending claims do not address the rejection of record.

Art Unit: 1647

9. The rejection of claim 23 is reapplied to claim 36 with respect to suitable carrier.

Claim Rejections - 35 USC § 102, maintained.

10. The rejection of claims 1-6, 9, 11 and 23 under 35 U.S.C 102(b) as being anticipated by Day et. al. is withdrawn and reapplied to claims 29-31 and 34-36 for reasons set forth in the Office Action dated 8/23/05. Applicants arguments presented in the response filed 11/28/05 is not found to be persuasive because SEQ ID NO: 1 provided by the Applicants is directed to a nucleotide sequence. Instant claims are drawn to an interferon polypeptide and thus the prior art anticipates the instant invention. Therefore, the rejections of record are maintained.

Claim Rejections - 35 USC § 103

11. The rejection of claims 7, 8 and 24 under 35 U.S.C 103 as being unpatentable over Day et al. in view of Olsen et al. (U. S. Patent No. 6, 114, 145) and Nasoff et al. (1999) is withdrawn and reapplied to claims 32 and 37 for reasons set forth in the Office Action dated 8/23/05 and argued above in paragraph 10 above.

New objections and rejections

12. The use of the trademark INFERGEN (p.4), has been noted in this application. This should be capitalized wherever it appears and be accompanied by the generic terminology.

13. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

14. The attempt to incorporate subject matter into this application by reference to U.S. Patent Nos. 4, 695, 623 or 4, 897, 471 is ineffective because Applicants have not indicated which interferon described in the specification of the allowed patent is compared to in the instant specification and claims (See MPEP § 608.01(p)). Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky, 474 F.2d671, 177 USPQ 144 (CCPA 1973). 37 CFR 1.57(b)(1) limits a proper incorporation by reference (except as provided in 37 CFR 1.57(a)) to instances only where the perfecting words "incorporated by reference" or the root of the words "incorporate" (e.g., incorporating, incorporated) and "reference" (e.g., referencing) appear. The requirement for specific root words will bring greater clarity to the record and provide a bright line test as to where something is being referred to is an incorporation by reference. The Office intends to treat references to documents that do not meet this "bright line" test as noncompliant incorporations by reference and may require correction pursuant to 37CFR 1.57(g). If a reference to a document does not clearly indicate an intended incorporation by reference, examination will proceed as if no incorporation by reference statement has been made and the Office will not expend resources trying to determine if

Art Unit: 1647

an incorporation by reference was intended. In addition to other requirements for an application, the referencing application must include an identification of the referenced patent, application, or publication (See 37 CFR 1.57(b)(2)). Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. " Essential material " may be incorporated by reference, but only by way of an incorporation by reference to a U.S. patent or U.S. patent application publication, which patent or patent application publication does not itself incorporate such essential material by reference. "Essential material " is material that is necessary to:

- (1) Provide a written description of the claimed invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and set forth the best mode contemplated by the inventor of carrying out the invention as required by the first paragraph of 35 U.S.C. 112;
- (2) Describe the claimed invention in terms that particularly point out and distinctly claim the invention as required by the second paragraph of 35 U.S.C. 112; or
- (3) Describe the structure, material, or acts that correspond to a claimed means or step for performing a specified function as required by the sixth paragraph of 35 U.S.C. 112. (See 37 CFR 1.57(c)). Appropriate correction is required.

14. Claim 29 is objected to because of the following informalities: The Applicants have followed used an incorrect format to report "Seq. ID No.: 1". The claims need to be

Art Unit: 1647

written in the correct format "SEQ ID NO: 1" (see MPEP 2423.3). In addition there multiple periods present within claim 1. Appropriate correction is required.

15. Claims 34 and 36 are objected to because of the following informalities: Claims 34 and 36 are dependent on cancelled claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112, second paragraph

16. Claims 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

16a. Claim 30 recites the limitation "interferon" in line 1. There is insufficient antecedent basis for this limitation in the claim because it is not clear which interferon applicant is referring to in claim 29 (Is it the interferon of SEQ ID NO: 1 or the interferon described in the U.S. Patent Nos. 4,695,623 or 4,897,471).

16b. Claims 29 is rejected under 35 U.S.C 112, second paragraph, as being vague and indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants appear to be defining an interferon polypeptide by nucleotide sequence of SEQ ID NO: 1. It is unclear how a polypeptide can be defined by nucleotide sequence. Claims 30-37 are rejected insofar as they are dependent on rejected claim 29. Note: Applicants recitation of "with higher efficacy than all interferons" does not contribute to the patentability of the present invention and would indeed raise 112, first paragraph issues. A recombinant interferon

Art Unit: 1647

of SEQ ID NO: "X", if free of prior art would be considered patentable. The associated biological functions will be inherent to the polypeptide.

Conclusion

17. No Claims are allowable.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

Art Unit: 1647

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JS 03/06

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud